# **EXHIBIT A**

# EXHIBIT A-1

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** aaiPharma Inc., 2320 Scientific Park Drive Wilmington, NC 28405.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:		Date and Time:			
GoldenbergLaw, PLLC, 800	-	N. 1 45 20	20		
2150, Minneapolis, MN 5540	)1	November 15, 20	20		
Inspection of Premises: Y	OU ARE COMMAN	DED to permit en	try onto th	ne designated	premises.
land or other property posses					
that the requesting party may	inspect, measure, surv	ey, photograph, te	st, or samp	ole the proper	rty of any
designated object or operation	ı on it.				
DI		D 1/17			
Place:		Date and Time:			
The following provisi	ons of Fed. R. Civ. 45	5 are attached – R	ule 45(c), 1	relating to the	place of
compliance; Rule 45(d), relatir			` , ,		
(g), relating to you duty to resp	pond to this subpoena	and the potential c	onsequenc	es of not doin	ıg so.
Date: <u>10/15/2020</u>	_				
	CLERK OF COUR				
		OR	1-1	M1	т
Goldenberg			<u>/s/</u>	Marlene	<u>J.</u>
Goldenberg	Signature of Clerk or I	Detruty Clerk	Attorn	ey's signature	
	Signature of Carris of I	συρίκη Διοπο	2 1000111	cy's signaunic	
The name, address, e-mail add	ress, and telephone nu	mber of the attorn	ey represen	ting the Plain	tiffs, who
have issued the requests or sul	bpoena are:				
Marlene J. Goldenberg, Golde	9				
mjgoldenberg@goldenberglav	v.com; scheriff(	<u>@goldenberglaw.co</u>	<u>om</u>	(legal a	assistant);

### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

## **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

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- drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-2

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

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# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Alcame Corporations (formerly AAlpharma Services Corp.), Alcame Corporation, 145 Fieldcrest Avenue, Edison, NJ 08837

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by ye	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
	5 are attached – Rule 45(c), relating to the place of s a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
CLERK OF COUR	T
	OR
Signature of Clerk or I	

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
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      - (i) is a party or a party's officer; or
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    - (2) For Other Discovery. A subpoena may command:
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      - (B) inspection of premises at the premises to be inspected.
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    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
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#### **SCHEDULE A**

#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

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electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

### DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-3

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

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IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Altus Formulation, 17 800 rue Lapointe, Mirabel (Quebec), Canada J7J 0W8

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
Signature of Clerk or	Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### **SCHEDULE A**

#### A. Definitions

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electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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Document 652-5

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- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.

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- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

Document 652-5

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-4

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

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# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Amsal Chem Pvt. Ltd., Plot # A, 401-402, Brahmanpuri, GIDC, Ankleshwar GIDC, Ankleshwar, Gujarat 393002, India

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Signature of Clerk or	Deputy Clerk Attorney's signature
	OR
CLERK OF COUL	RT
Date:	-
(g), relating to you duty to respond to this subpoens	1 , 1
	45 are attached – Rule 45(c), relating to the place of as a person subject to a subpoena; and Rule 45(e) and
Place:	Date and Time:
designated object or operation on it.	
	vey, photograph, test, or sample the property of any
	you at the time, date and location set forth below, so
1	NDED to permit entry onto the designated premises
Suite 2150, Minneapolis, MN 55401	November 15, 2020
	NI15 2020
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

# **RELEVANT PORTIONS OF FED. R. CIV. P. 45**

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

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#### DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### **ANDA** and **DMF** File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **Testing Data**

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.

Document 652-5

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- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.
- 5. All documents related to any inspection conducted by You, or for which you (or employees working on your behalf) were present of any of the following facilities, including, but not limited to, photographs, documents collected, video recordings, audio recordings, emails, travel receipts, itineraries, visa requests, and the like
  - a) Unit III (FEI: 3005406526)
  - b) Unit V (FEI: 3008307735)
  - c) Unit IX (FEI: 3009093782)
  - d) Gaddapotharam (FEI: 2004378446)

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-5**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND
IBESARTAN PRODUCTS LIABILITY
LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Avantor, 222 Red School Lane, Phillipsburg, NJ 08865

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so evey, photograph, test, or sample the property of any
Place:	Date and Time:
	45 are attached – Rule 45(c), relating to the place of as a person subject to a subpoena; and Rule 45(e) and a and the potential consequences of not doing so.
CLERK OF COU	RT
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or	Deputy Clerk Attorney's signature
	1 C.1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

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#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

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- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

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electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-6

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND
IBESARTAN PRODUCTS LIABILITY
LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: AXIS Clinicals Ltd., 1711 Highway 10 East, Dilworth, Minnesota 56304

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANIand or other property possessed or controlled by you that the requesting party may inspect, measure, survive designated object or operation on it.	
Place:	Date and Time:
The following provisions of Fed. R. Civ. 45 compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020	1 ,
CLERK OF COUR'	Т
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature
The name address a grail address and talenhous as	1 61 1 11 11 166 1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
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  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
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- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

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electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

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14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-7

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16062

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** AXIS Clinicals Ltd., Abhijit Chaudhari, 1-1211/1, Survey no. 66 (part) & 67 (part), Miyapur, Serilingampally, Hyderabad 50049, India

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	DED to permit entry onto the designated premises, you at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
0 1	
Signature of Clerk or	Deputy Clerk Attorney's signature
	1 0.1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- - (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

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- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory

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- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication

consultants or the like) related to the manufacture of any ARB drug.

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- d. Basis of Privilege

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- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

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- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-8

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16073

IN RE: VALSARTAN, LOSARTAN, AND
IBESARTAN PRODUCTS LIABILITY
LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

## SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Azbil Telstar Technologies Registered Agent, 1504 Grundy Ln, Bristol, PA 19007

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena Date: 10/15/2020	
CLERK OF COUR	
	OR 
Signature of Clerk or	, ·

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

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preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

- drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- 11. All notes, recordings, images, reports, memoranda, internal or external communications, or other documents created or produced by you in regard to the audit conducted by you at the facility of Zhejiang Huahai Pharmaceutical Co. Ltd., Chuannan Site No. 1 Branch Factory, Coastal Industrial Zone, Duqiao, Linhai, Zhejiang 317016.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by you related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.

- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- **4.** All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-9

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

## SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** CABB AG Registered Agent, c/o Seth A. Goldberg 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so rvey, photograph, test, or sample the property of any
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection (g), relating to you duty to respond to this subpoen Date: 10/15/2020	
CLERK OF COU	
	OR
Signature of Clerk or	/s/ Marlene J. Goldenberg  r Deputy Clerk  Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
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#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.
- 4. Any contracts, purchase orders or invoices concerning the sale from you to any Defendant of any goods, materials, chemicals or other tangible items related to or used in the manufacture of any ARB drug or any component thereof.

#### **Communications with Relevant Parties**

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- 11. All documents, reports or communications concerning any testing, analysis, audits or inspections for the formation or presence of nitrosamines which were performed by you, on your behalf or at the direction of others of any process, equipment, goods, or facilities under your control and utilized in the manufacture of Valeryl Chloride.

#### Recall-Related Documents

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.

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- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-10

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

## SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Cambrex, One Meadowlands Plaza, East Rutherford, NJ 07073

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANI land or other property possessed or controlled by you that the requesting party may inspect, measure, surv designated object or operation on it.	
Place:	Date and Time:
The following provisions of Fed. R. Civ. 45 compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena 2 Date: 10/15/2020 CLERK OF COUR'	and the potential consequences of not doing so.  T  OR
Signature of Clerk or I	

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### **RELEVANT PORTIONS OF FED. R. CIV. P. 45**

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
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Document 652-5

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#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Document 652-5

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-11

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Catalent, Inc., 14 Schoolhouse Road Somerset, NJ 08873.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANIand or other property possessed or controlled by you that the requesting party may inspect, measure, survive designated object or operation on it.	
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR	OR /s/ Marlene J.
Goldenberg Signature of Clerk or 1	<del></del>
The name, address, e-mail address, and telephone numbers issued the requests or subpoena are:  Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 imigoldenberg@goldenberglaw.com;  scheriff(	, .

### RELEVANT PORTIONS OF FED. R. CIV. P. 45

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Document 652-5

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### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

Document 652-5

PageID: 16115

- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-12

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16117

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Catalent Micron Technologies, Inc., c/o Registered Agent, Seth Goldberg, 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:
Catalent Micron Technologies, Inc., Analytical	
Services, 333 Phoenixville Pike, Malvern, PA	December 8, 2020
19355	

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so. Date: 10/15/2020

CLERK OF COURT

OR

/s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Case 1:19-md-02875-RMB-SAK

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### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### **SCHEDULE A**

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.
- **4.** Any purchase orders or statements of work related to the physical and chemical testing of ARB API, excipients or Finished Dose drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- **11.** Any testing protocols, methods or method validation information submitted to you by or on behalf of any Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- **12.** All images of any ARB API or Finished Dose drug submitted to you by or on behalf of any Defendant.

13. Any samples of any ARB API or Finished Dose drug submitted to you by or on behalf of any Defendant that have been maintained by you.

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#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.

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- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-13

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Charles Wang c/o Seth Goldberg, esq., Duane Morris

GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

land or other property pos	ssessed or controlled by you at the timnay inspect, measure, survey, photogra	mit entry onto the designated premises, e, date and location set forth below, so ph, test, or sample the property of any
Place:	Date and T	ime:
compliance; Rule 45(d), re		d – Rule 45(c), relating to the place of bject to a subpoena; and Rule 45(e) and ntial consequences of not doing so.
		OR
		/s/ Marlene J. Goldenberg
	Signature of Clerk or Deputy Clerk	Attorney's signature
The name, address, e-mail	<u> </u>	attorney representing the Plaintiffs, who

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

Place:

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    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
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- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

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- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### General

1. A copy of your most current CV.

### **Corporate Organization**

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by Defendant ZHP to perform work related to a toxicology assessment.
- 2. Any document evidencing the scope or nature or work you performed for Defendant ZHP (including any contracts) that related to a toxicology assessment (either formal, or informal).

1. .

#### **Nitrosamine Contamination**

1. All communications between you and any Defendant relating to nitrosamines.

{Cases: 00032516.DOCX}

- 2. All communications between you and any Defendant concerning any toxicology assessment.

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- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding nitrosamines
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All documents or communications relating to nitrosamine testing of any drug, including any nitrosamine testing provided to you by any Defendant.
- 9. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### Communications with the FDA

1. Documents sufficient to show whether You ever communicated on behalf of Defendant ZHP with the FDA with regards to nitrosamine impurities and/or the toxicological assessment of NDMA (including the determination of an acceptable daily limit)

#### Communications with Other Third Parties

- 1. All communications between you and Zi-Qiang regarding Defendant ZHP and/or any toxicology assessment conducted by you on behalf of Defendant ZHP.
- 2. All communications between you and Frederick Ball (or any person working for Frederick Ball) regarding Defendant ZHP and/or any toxicology assessment conducted by you on behalf of Defendant ZHP. .
- 3. All communications between you and Dylan Yao regarding Defendant ZHP and/or any toxicology assessment conducted by you on behalf of Defendant ZHP.
- 4. All communications between you and any employees of Alavanda Consulting, including, but not limited to Derek Zhang, regarding Defendant ZHP and/or any toxicology assessment conducted by you on behalf of Defendant ZHP.

### **Testing Data**

Documents sufficient to show whether You conducted any independent testing of API for nitrosamine impurity, and/or whether you conducted any independent AMES or DEREK testing on behalf of ZHP to assess the genotoxic potential or toxicological impact of a nitrosamine contamination.

# Toxicology Analysis and/or Assessment

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use and/or review in anticipation of preparing any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs, including, but not limited to, any testing results of nitrosamine levels in API, DEREK and/or AMES testing.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 5. All toxicology assessments, including all draft reports, final reports, redlined reports related to the nitrosamine impurity in ZHP's drugs.

# EXHIBIT A-14

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Chemir Pharma Services, 2672 Metro Blvd., Maryland Heights, MO 63043.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by ye	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena Date: 10/15/2020	
CLERK OF COUR	OR
Goldenberg	
Signature of Clerk or I	Deputy Clerk Attorney's signature
have issued the requests or subpoena are:	mber of the attorney representing the Plaintiffs, who
	LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, <u>@goldenberglaw.com</u> (legal assistant);

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

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#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

## **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-15

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16150

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY **LITIGATION** 

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Chemo Group India, c/o Seth A. Goldberg 30 South 17th Street, Philadelphia, PA 19103-4196

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020
DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Date and Time:
5 are attached – Rule 45(c), relating to the place of as a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
T
OR

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

# RELEVANT PORTIONS OF FED. R. CIV. P. 45

Document 652-5

PageID: 16151

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by you related to any and all Sartan products.

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- 5. Any documents related to credits or refunds anticipated or issued for the return of any ARB API or Finished Dose drug from any Defendant or other party to you.
- **6.** Any documents related to credits or refunds anticipated or issued for the return of any ARB API or Finished Dose drug from you to any Defendant.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.

3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

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**4.** All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-16

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16161

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite

have issued the requests or subpoena are:

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Cobalt Pharmaceuticals Inc., 6733 Mississauga Rd., Suite 400 Mississauga, L5N 6J5 Canada.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 5540	1 November 15,	2020
land or other property possess	OU ARE COMMANDED to permit sed or controlled by you at the time, d inspect, measure, survey, photograph, on it.	ate and location set forth below, so
Place:	Date and Times	:
compliance; Rule 45(d), relatin	ons of Fed. R. Civ. 45 are attached – g to your protection as a person subjection to this subpoena and the potential CLERK OF COURT  OR  Signature of Clerk or Deputy Clerk	ct to a subpoena; and Rule 45(e) and
The name, address, e-mail add	ress, and telephone number of the attor	

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
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  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

Document 652-5

PageID: 16165

#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

## **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-17

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Cybernetik Technologies P Ltd., 303 Mahatma Coop Hsg Soc, Near Gandha Bhavan, Kothrud, Pune 411038, India

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so evey, photograph, test, or sample the property of any
Place:	Date and Time:
0 1	RT
	OR
Signature of Clerk or	Deputy Clerk Attorney's signature
	1 61 1 1 11 166 1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
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electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-18

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Dohmen Life Science Services, LLC, c/o Registered Agent, Cynthia A. Laconte, 800 Woodland Prime, Ste 200, W127N7564 Flint Dr, Menomonee Falls, WI 53051.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020
NDED to permit entry onto the designated premises you at the time, date and location set forth below, so evey, photograph, test, or sample the property of any
Date and Time:
45 are attached – Rule 45(c), relating to the place of as a person subject to a subpoena; and Rule 45(e) and a and the potential consequences of not doing so.
RT
OR
/s/ Marlene J. Goldenberg_
Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity, including Eversana Life Science Services, LLC, of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which

information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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5. All recall status reports, documents relied upon in the preparation of the recall status reports and all communications concerning the recall status reports in regard to all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

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# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### Toxicology Assessments

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-19

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Douglas Campbell, c/o InterProQRA, 120 Route 17 North, Paramus, NJ 07652

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

T DI	D 187
Place:	Date and Time:
Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by ye	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
0 <b>1</b>	T
	OR
Signature of Clerk or I	
The name address a mail address and telephone nu	mbou of the attourner uppresenting the Digitiffs who

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd. (Z; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

### **DOCUMENT TO BE PRODUCED**

#### General

1. A copy of your most current CV.

#### **Contracts**

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.
- **4.** Contracts with ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD. regarding services being provided for cGMP services.

5. Any contracts executed by you on behalf of Zhejiang Huahai Pharmaceutical Co. Ltd. for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any drug.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### **Communications with Other Third Parties**

- 1. All communications between you and Zi-Qiang regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.
- 2. All communications between you and Frederick Ball (or any person working for Frederick Ball) regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.
- 3. All communications between you and Peter Saxon regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.
- 4. All communications between you and Charles Wang regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.
- 5. All communications between you and Derek Zhang regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.
- 6. All communications between you and Dylan Yao regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.
- 7. All communications between you and any other person, including former or current FDA inspectors regarding Zhejiang Huahai Pharmaceutical Co. Ltd. or the nitrosamine contamination.

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.

- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- **11.** All communications between you and Zhejiang Huahai Pharmaceutical Co. Ltd. regarding the FDA's investigation into the Nitrosamine Contamination.
- 12. All documents (either in final or draft form) in your possession regarding the FDA's investigation into the Nitrosamine contamination.
- 13. All notes taken during meetings and/or phone calls with the FDA regarding the nitrosamine contamination.
- 14. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination and/or Zhejiang Huahai Pharmaceutical Co. Ltd.'s manufacture of Valsartan, or Irbesartan.
- 15, Any notes, memoranda, images, reports or other documents concerning

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.

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- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.

6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

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# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

#### **Inspection Documents**

- 1. All communications between You and Zhejiang Huahai Pharmaceutical Co. Ltd. regarding the FDA inspections of the following Zhejiang Huahai Pharmaceutical Co. Ltd. Facilities:
  - a. Xunqiao (FEI: 3003999190)
  - b. Chuannan (FEI: 3003885745)
- 2. All communications between You and employees at the FDA, including but not limited to, Milind Ganjawala, regarding inspections related to the following Zhejiang Huahai Pharmaceutical Co. Ltd. facilities:
  - a. Xunqiao (FEI: 3003999190)
  - b. Chuannan (FEI: 3003885745)
- 3. All documents related to any FDA inspection conducted by You, or witnessed by you, of any of the following facilities, including, but not limited to, notes, photographs, documents collected, video recordings, audio recordings, emails, travel receipts, itineraries, visa requests, and the like
  - a. Xunqiao (FEI: 3003999190)
  - b. Chuannan (FEI: 3003885745)

#### January 29-31 Audit

- 1. All documents related to the January 29-31 inspection conducted by You of FEI:3003885745, including, but not limited to, notes, photographs, documents collected, video recordings, and audio recordings.
- 2. Documents sufficient to show all persons you spoke to during the January 29-31 audit.
- 3. All documents in your possession collected during the January 29-31 audit including, but not limited to all documents cited in Section 4.1.3 of your April 29, 2019, final report.
- 4. All Communications between You and Ziqiang Gu regarding the January 29-31 Audit.
- 5. All documents regarding your travel to China for the January 29-31, 2019 Audit, including, but not limited to, receipts, flight and travel itineraries, visa requests, and hotel bills.

# March 8-9 Audit

1. All Communications between You and Ziqiang Gu regarding the March 8-9, 2019 Audit.

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# **Evaluation of Quality Management System and CAPAs**

- 1. All communications between You, Zi-Qiang Gu, employees at Zhejiang Huahai Pharmaceutical Co. Ltd., and/or employees at Duane Morris regarding the April 29, 2019 Audit Report prepared by You and Zi-Qiang for Zhejiang Huahai Pharmaceutical Co. Ltd..
- 2. All documents reviewed and/or collected by you in preparation for your creation of the April 29, 2019 Audit Report.
- 3. All draft versions of the April 29, 2091, Audit Report in Your possession.

# **EXHIBIT A-20**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Envoy Health Care LLC, 800 Concourse Parkway South, Suite 200, Maitland, FL 32751.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:		Date and Time:			
GoldenbergLaw, PLLC, 800 L					
2150, Minneapolis, MN 55401	!	November 15, 2020			
Inspection of Premises: YC land or other property possesse that the requesting party may indesignated object or operation of the second	ed or controlled by your nspect, measure, surv	ou at the time, dat	te and locati	ion set forth belo	ow, so
Place:		Date and Time:			
The following provision compliance; Rule 45(d), relating (g), relating to you duty to respond to the control of	g to your protection as	s a person subject	to a subpoe	ena; and Rule 45(	(e) and
	CLERK OF COUR'	Т			
		OR			
			<u>/s/</u>	Marlene	J.
Goldenberg	Signature of Clerk or I	Deputy Clerk	Attorn	ey's signature	
The name, address, e-mail addr have issued the requests or sub Marlene I. Goldenberg, Golden	poena are:		, 1		
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scheriff@goldenberglaw.com

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
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- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

Document 652-5

PageID: 16211

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- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-21

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Eurofins Lancaster Laboratories, Inc., 2425 New Holland Pike, Lancaster, PA 17601

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	IDED to permit entry onto the designated premises, you at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena Date: 10/15/2020	
CLERK OF COUR	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or	,
777 11 11 1.11	1 Cd

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
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electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
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## **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

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# Communications with Relevant Parties

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- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-22

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

have issued the requests or subpoena are:

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Eversana Life Science Services, LLC Registered Agent, 17877 Chesterfield Airport Rd, Chesterfield, Missouri 63005

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

land or other property possess	sed or controlled by you at the tinspect, measure, survey, photo	permit entry onto the designated premises, time, date and location set forth below, so graph, test, or sample the property of any
Place:	Date and	l Time:
compliance; Rule 45(d), relatin	g to your protection as a person	ched – Rule 45(c), relating to the place of subject to a subpoena; and Rule 45(e) and otential consequences of not doing so.
	CLERK OF COURT	
		OR
		<u>/s/ Marlene J. Goldenberg</u>
	Signature of Clerk or Deputy Cler	k Attorney's signature
The name, address, e-mail add	ress, and telephone number of the	ne attorney representing the Plaintiffs, who

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity, including Dohmen Life Science Services, LLC, of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which

information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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5. All recall status reports, documents relied upon in the preparation of the recall status reports and all communications concerning the recall status reports in regard to all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.
- 6. Any ARB products or API remaining in your possession.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

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# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-23**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16240

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Dlagor

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Galbraith Laboratories, Inc., 2323 Sycamore Drive, Knoxville, TN 37921-1700

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Data and Time

Tiacc.	Bate and Time.
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMAN land or other property possessed or controlled by you	DED to permit entry onto the designated premises,
1 1 1 1	
that the requesting party may inspect, measure, surv	ey, photograph, test, or sample the property of any
designated object or operation on it.	
Place:	Date and Time:
The following provisions of End D. Civ. Al	5 are attached – Rule 45(c), relating to the place of
compliance; Rule 45(d), relating to your protection a	```
	1 ,
(g), relating to you duty to respond to this subpoena Date: _10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR	T
CLERK OF COUR	
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature
The many address a mail address and telephone ma	1 0.1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-24

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Gibralter Laboratories, Inc., 122 Fairfield Road, Fairfield, NJ 07004

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by ye	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
€ I	T OROR
The name address a mail address and telephone nu	umber of the attorney confecenting the Dlaintiffe who

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
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- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
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- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
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- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

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- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-25

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

## SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Gibralter Laboratories, Inc., 122 Fairfield Rd., Fairfield, NJ 07004.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANIand or other property possessed or controlled by you that the requesting party may inspect, measure, survidesignated object or operation on it.	
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR'	
	OR Marlene J.
Goldenberg Signature of Clerk or I	Deputy Clerk Attorney's signature
The name, address, e-mail address, and telephone numbers issued the requests or subpoena are:  Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 Imigoldenberg@goldenberglaw.com; scheriff@	

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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#### Α. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
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#### **Nitrosamine Contamination**

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- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

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- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

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#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-26

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16273

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Gintegra Group International LLC, USA, c/o Registered Agent: Plaza del Museo, Apto 1493 Ciudadela SJ, Puerto Rico 00919

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so evey, photograph, test, or sample the property of any
Place:	Date and Time:
0 1	
Signature of Clerk or	Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

PageID: 16277

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Document 652-5

PageID: 16280

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-27

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: ICON Laboratory Services, Inc., 8282 Halsey Road, Whitesboro, NY 13492

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

DI	TD . 17"
Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	N
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so rvey, photograph, test, or sample the property of any
Place:	Date and Time:
~ ·	,
Signature of Clerk or	· ·
The name address a mail address and telephone	wamber of the atterney representing the Disiptiffs who

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
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  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
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- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
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- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

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- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-28

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Integrated Analytical Laboratories, LLC, 273 Franklin Road, Randolph, NJ 07869.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:			
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite				
2150, Minneapolis, MN 55401	November 15, 2020			
Inspection of Premises: YOU ARE COMMANI and or other property possessed or controlled by you that the requesting party may inspect, measure, survidesignated object or operation on it.				
Place:	Date and Time:			
compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena :  Date: 10/15/2020	and the potential consequences of not doing so.			
CLERK OF COUR'				
	OR Marlene J.			
Goldenberg Signature of Clerk or I				
The name, address, e-mail address, and telephone numbers issued the requests or subpoena are:  Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 Imigoldenberg@goldenberglaw.com; scheriff@				

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
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preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-29

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** International Trading Pharmaceuticals Laboratories, Inc., 470 Chamberlain Avenue, Suite 12, Paterson, NJ, 07522.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

Inspection of Premises: YO land or other property possesses that the requesting party may in designated object or operation o	d or controlled by yourspect, measure, surv	ou at the time, dat	e and location	on set forth belo	w, so
Place:		Date and Time:			
The following provision compliance; Rule 45(d), relating (g), relating to you duty to respondate: _10/15/2020	to your protection as	s a person subject and the potential c	to a subpoer	na; and Rule 45(	e) and
	CLEIU OI COCK	OR			
			/s/	Marlene	<u>J.</u>
Goldenberg	Signature of Clerk or 1	Deputy Clerk	Attorne	v's signature	-

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

Case 1:19-md-02875-RMB-SAK Document 652-5 Filed 12/04/20 Page 315 of 744 PageID: 16307

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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#### Α. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-30

#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY **LITIGATION** 

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

#### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Jost Chemical Co., 8150 Lackland Rd., St. Louis, MO 63114.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite	Bace and Time.
2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANIand or other property possessed or controlled by you that the requesting party may inspect, measure, survive designated object or operation on it.	
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR'	
	OR /s/ Marlene J.
Goldenberg Signature of Clerk or I	
The name, address, e-mail address, and telephone numbave issued the requests or subpoena are:  Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 imigoldenberg@goldenberglaw.com;  scheriff(	

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

PageID: 16322

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-31

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16329

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Jubilant Generics, 790 Township Line Road, Suite 175, Yardley, PA 19067.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

DI	D . 177
Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite	N15 2020
2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
CLERK OF COOK	OR
	/s/ Marlene J.
Goldenberg	
Signature of Clerk or i	Deputy Clerk Attorney's signature
have issued the requests or subpoena are:	mber of the attorney representing the Plaintiffs, who
	LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, <u>@goldenberglaw.com</u> (legal assistant);

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
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- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
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- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
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- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
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- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
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- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### SCHEDULE A

Document 652-5

PageID: 16333

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- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-32

#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16340

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

#### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Lantech Pharmaceutical Ltd., c/o Mr. V Prakash Reddy, Managing Director, Lantech Pharmaceuticals Limited, H. No. 7-2-1735 & 1813/5/A1, Flat 101SBH Building, CZECH Colony, Street No. 2Sanath Nagar, Hyderabad 500018 Telangana India

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 L Suite 2150, Minneapolis, MN 5	*	15, 2020
Inspection of Premises: YC land or other property possesses	OU ARE COMMANDED to pered or controlled by you at the timespect, measure, survey, photogra	mit entry onto the designated premises, as, date and location set forth below, so aph, test, or sample the property of any
Place:	Date and T	ime:
compliance; Rule 45(d), relating	to your protection as a person su and to this subpoena and the pote CLERK OF COURT	ed – Rule 45(c), relating to the place of abject to a subpoena; and Rule 45(e) and ential consequences of not doing so.
	Signature of Clerk or Deputy Clerk	Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

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#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### **ANDA** and **DMF** File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-33

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Lantech Pharmaceuticals, H.NO. 7-2-1735&1813/A1, 1ST FLOOR, STREET NO. 2, CZECH COLONY, SBH BUILDING, SANATH NAGAR HYDERABAD, INDIA

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
0 1	
Signature of Clerk or	

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-34

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Linhai Huanan Chemical Co., Ltd. Registered Agent, c/o Seth Goldberg, 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite	1 47 2020
2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by ye	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
	5 are attached – Rule 45(c), relating to the place of s a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
CLERK OF COUR	T
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

PageID: 16367

#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
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#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- **11.** All documents prepared by you or on your behalf related to evaluations or assessments for nitrosamine formation in any process used by you in the manufacture of starting materials supplied to any Defendant concerning an ARB API or Finished Dose drug.

#### Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.

- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

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4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- Documents sufficient to show all meetings, and/or verbal communications had between You
  and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting
  requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.

3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

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4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-35

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Malvern Instruments Registered Agent, c/o Seth Goldberg, 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMAN land or other property possessed or controlled by yethat the requesting party may inspect, measure, surv designated object or operation on it.	
Place:	Date and Time:
The following provisions of Fed. R. Civ. 4st compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena Date: 10/15/2020	1 ' '
CLERK OF COUR	Т
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

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- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

5. All documents related to any testing or analysis conducted by you of any ARB API or ARB Finished Dose drug for particle size or particle size distribution.

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#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-36

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Medical Affairs Company, c/o Rich Murphy, PharmD, Director, Medical Communications, The Medical Affairs Company, 125 TownPark Drive, Suite 450, Kennesaw, GA 30144

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so arvey, photograph, test, or sample the property of any
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection	45 are attached – Rule 45(c), relating to the place of a sa a person subject to a subpoena; and Rule 45(e) and na and the potential consequences of not doing so.  JRT  OR
Signature of Clerk o	/s/ Marlene J. Goldenberg

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### **RELEVANT PORTIONS OF FED. R. CIV. P. 45**

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

## **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

## Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

PageID: 16395

# EXHIBIT A-37

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Meridan Consulting, 300 Carnegie Center Drive, #150, Princeton, NJ 08540

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

testing, or sampling of the material: See attached Sch	edule A
Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMAN	DED to permit entry onto the designated premises,
ı	ou at the time, date and location set forth below, so
1 1 11	vey, photograph, test, or sample the property of any
designated object or operation on it.	
Place:	Date and Time:
© 1	5 are attached – Rule 45(c), relating to the place of
	s a person subject to a subpoena; and Rule 45(e) and
(g), relating to you duty to respond to this subpoena	and the potential consequences of not doing so.
Date: 10/15/2020	75
CLERK OF COUR	
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature
	and on of the attenue or nonnegatine the Disintiffe and

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

## **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

## Solvent Manufacturing, Recovery, and Recycling

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- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-38**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite

have issued the requests or subpoena are:

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: MSN Laboratories Pvt. Ltd., MSN House, Plot No C-24 Industrial Estate, Sanathnagar Hyderabad, 500018 India.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled b	ANDED to permit entry onto the designated premises by you at the time, date and location set forth below, so survey, photograph, test, or sample the property of any
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection	v. 45 are attached – Rule 45(c), relating to the place of on as a person subject to a subpoena; and Rule 45(e) and ena and the potential consequences of not doing so.  OURT'  OR
Signature of Clerk	c or Deputy Clerk  Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
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- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
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- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

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#### Α. **Definitions**

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- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
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- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

## **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-39

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Novartis Pharmaceuticals, Corporation, One Health Plaza, Building 100, East Hanover, NJ 07936

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by	NDED to permit entry onto the designated premises, you at the time, date and location set forth below, so rvey, photograph, test, or sample the property of any
Place:	Date and Time:
3	OR
Signature of Clerk or	/s/ Marlene J. Goldenberg Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

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#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-40**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Novartis Registered Agent, 1 Health Plaza East Hanover, NJ 07936-1080

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMAN land or other property possessed or controlled by yethat the requesting party may inspect, measure, survidesignated object or operation on it.	
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena Date: 10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR	OR
Signature of Clerk or I	/s/ Marlene J. Goldenberg

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### **SCHEDULE A**

Document 652-5

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

## **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

Document 652-5

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-41

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Perritt Laboratories, Inc., 145 South Main Street, Highstown, NJ 05820

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place: GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401  Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premise land or other property possessed or controlled by you at the time, date and location set forth below, s that the requesting party may inspect, measure, survey, photograph, test, or sample the property of an designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so. Date: 10/15/2020		
Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premise land or other property possessed or controlled by you at the time, date and location set forth below, set that the requesting party may inspect, measure, survey, photograph, test, or sample the property of an designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached — Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so. Date: 10/15/2020	Place:	Date and Time:
Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premise land or other property possessed or controlled by you at the time, date and location set forth below, s that the requesting party may inspect, measure, survey, photograph, test, or sample the property of an designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date: 10/15/2020	GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
land or other property possessed or controlled by you at the time, date and location set forth below, set that the requesting party may inspect, measure, survey, photograph, test, or sample the property of an designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date: 10/15/2020	Suite 2150, Minneapolis, MN 55401	November 15, 2020
The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) an (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so. Date: 10/15/2020	land or other property possessed or controlled by y that the requesting party may inspect, measure, surv	you at the time, date and location set forth below, so
compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) an (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so. Date: 10/15/2020	Place:	Date and Time:
	compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena	as a person subject to a subpoena; and Rule 45(e) and
	CLERK OF COUR	
OR		
Signature of Clerk or Deputy Clerk Attorney's signature	Signature of Clerk or	Deputy Clerk Attorney's signature
The name address a mail address and telephone number of the attorney representing the Plaintiffs wh		1 C.1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
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- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### **ANDA** and **DMF** File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- Document 652-5 PageID: 16449
- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-42

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Prevalere Life Sciences Inc., 8282 Halsey Road, Whitesboro, NY 13492.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANIand or other property possessed or controlled by you that the requesting party may inspect, measure, survices designated object or operation on it.	
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR	
	OR Marlene
Goldenberg Signature of Clerk or 1	Deputy Clerk Attorney's signature
The name, address, e-mail address, and telephone numbave issued the requests or subpoena are:  Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 imigoldenberg@goldenberglaw.com;  scheriff(	

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
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- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### **SCHEDULE A**

Document 652-5

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#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-43

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Prinbury Biopharm Co., Ltd Registered Agent c/o Seth Goldberg, 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

			entry onto the designated premises, late and location set forth below, so
			test, or sample the property of any
designated object or operatio	n on it.		
The state of the s		7	
Place:		Date and Time:	
compliance; Rule 45(d), relati	ing to your protection as	s a person subject	Rule 45(c), relating to the place of ct to a subpoena; and Rule 45(e) and l consequences of not doing so.
Date: 10/15/2020	spond to this subpoena i	and the potentia	reonsequences of not doing so.
	CLERK OF COURT	Γ	
		OR	
			/s/ Marlene J. Goldenberg
	Signature of Clerk or L	Deputy Clerk	Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### **RELEVANT PORTIONS OF FED. R. CIV. P. 45**

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-44

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** ProPharma Group, Inc. Registered Agent, c/o Seth Goldberg, 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

DED to permit entry onto the designated premises, on at the time, date and location set forth below, so ey, photograph, test, or sample the property of any
Date and Time:
are attached – Rule 45(c), relating to the place of a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
OR
1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

## EXHIBIT A-45

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Qualanex, 1401 Harris Road, Libertyville, IL 60048

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Suite 2150, Minneapolis	s, MN 55401	November 15,	2020
land or other property p	ossessed or controlled	by you at the time, d	entry onto the designated premises, ate and location set forth below, so test, or sample the property of any
designated object or ope			the state of the s
		T = 1 = 1	
Place:		Date and Time:	:
© I			Rule 45(c), relating to the place of
1	<i>.</i> .	· /	et to a subpoena; and Rule 45(e) and
Date: $10/15/2020$	o respond to this subject	bena and the potentia	l consequences of not doing so.
Date. 10/15/2020	CLERK OF CO	OURT	
		OR	
_		_/s/	Marlene J. Goldenberg
	Signature of Cleri	k or Deputy Clerk	Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### **RELEVANT PORTIONS OF FED. R. CIV. P. 45**

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  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
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    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
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    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
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- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of

business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### **Communications with Relevant Parties**

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.

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- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by Stericycle, Inc. related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-46

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite

have issued the requests or subpoena are:

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

#### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Ratiopharm, Graf-Arco-Strasse 3 Ulm, D-89079 Germany.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020	
land or other property possessed or controlled b	ANDED to permit entry onto the designated premise by you at the time, date and location set forth below, survey, photograph, test, or sample the property of an	
Place:	Date and Time:	
compliance; Rule 45(d), relating to your protectio	7. 45 are attached – Rule 45(c), relating to the place of as a person subject to a subpoena; and Rule 45(e) are ena and the potential consequences of not doing so.  URT  OR	
Signature of Clerk	Signature of Clerk or Deputy Clerk  Attorney's signature	
The name, address, e-mail address, and telephone	e number of the attorney representing the Plaintiffs, wh	

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# SCHEDULE A

Document 652-5

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#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
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preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
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- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

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# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

# Communications with Relevant Parties

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- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
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- 6. All draft reports edited by you for comment and provided to any Defendant.
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- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
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- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

## **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-47

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Return Logistics International Corporation Registered Agent, 22 Artley Rd, Savannah, Georgia 31408

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

land or other property poss	essed or controlled by you at the ti ay inspect, measure, survey, photog	ermit entry onto the designated premises, ime, date and location set forth below, so graph, test, or sample the property of any
Place:	Date and	Time:
compliance; Rule 45(d), rela	ting to your protection as a person	hed – Rule 45(c), relating to the place of subject to a subpoena; and Rule 45(e) and tential consequences of not doing so.  OR
	Signature of Clerk or Deputy Clerk	/s/ Marlene J. Goldenberg

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-48

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16517

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Rising Pharmaceuticals, 2 Tower Center Blvd., Suite 1401A, East Brunswick, NJ 08816

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place: GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401  Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date: 10/15/2020  CLERK OF COURT  OR  /s/ Marlene J. Goldenberg  Attorney's signature		
Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date: 10/15/2020  CLERK OF COURT  OR  /s/ Marlene J. Goldenberg	Place:	Date and Time:
Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date: 10/15/2020  CLERK OF COURT  OR  /s/ Marlene J. Goldenberg	GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.  Place:  Date and Time:  The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date: 10/15/2020  CLERK OF COURT  OR  /s/ Marlene J. Goldenberg	Suite 2150, Minneapolis, MN 55401	November 15, 2020
The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date:	land or other property possessed or controlled by y that the requesting party may inspect, measure, sur	you at the time, date and location set forth below, so
compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.  Date:	Place:	Date and Time:
OROR	compliance; Rule 45(d), relating to your protection a (g), relating to you duty to respond to this subpoena	as a person subject to a subpoena; and Rule 45(e) and
	CLERK OF COUR	RT
·		OR
Signature of Clerk or Deputy Clerk Attorney's signature		
	Signature of Clerk or	Deputy Clerk Attorney's signature
The name address a mail address and telephone number of the attorney representing the Plaintiffs who		1 (1 ) (1 )

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

## **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-49

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Peter Saxon, Saxon International Associates Registered Agent, 10 De Bary Pl, Summit, NJ 07901

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANI land or other property possessed or controlled by you that the requesting party may inspect, measure, surv designated object or operation on it.	
Place:	Date and Time:
The following provisions of Fed. R. Civ. 45 compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020 CLERK OF COUR	and the potential consequences of not doing so.
Signature of Clerk or I	·

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
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  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
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  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
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- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
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- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

Document 652-5

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- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

## **DOCUMENT TO BE PRODUCED**

### General

1. A copy of your most current CV.

### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

# **Contracts**

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA

advocacy or communication, public relations relating to the ARB drug recalls, or recall management.

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- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.
- 4. Contracts with ZHP regarding services being provided for cGMP services.
- 5. Any contracts executed by you on behalf of ZHP for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any drug.

### **Communications with Relevant Parties**

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege
- **3.** All communications between you and employees at ZHP regarding the filing of Drug Master Files for API generally, and regarding DMF 020939 more specifically.
- **4.** All communications between you and persons at the FDA regarding the filing of Drug Master Files for API on behalf of ZHP, including but not limited to the filing of DMFs for the manufacture of Valsartan API

# ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.

7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.

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- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- **11.** All documents within your possession regarding the contamination of Valsartan, Losartan, and Irbesartan API with Nitrosamines.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

# Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make

- ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# Documents Regarding FDA Regulatory Compliance and cGMP's

1. All documents, including draft documents, notes, presentations, reports, memorandums created by you and provided to ZHP regarding issues related to the FDA and compliance with cGMPs.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

## **Toxicology Assessments**

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.

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- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **Inspection Documents**

- 1. All communications between You and ZHP regarding the FDA inspections of the following **ZHP** Facilities
  - a. Xunqiao (FEI: 3003999190)
  - **b.** Chuannan (FEI: 3003885745)
- 2. All communications between You and employees at the FDA, including but not limited to, Milind Ganjawala, regarding inspections related to the following ZHP facilities
  - a. Xunqiao (FEI: 3003999190)
  - **b.** Chuannan (FEI: 3003885745)
- 3. All documents related to any FDA inspection conducted by You, or witnessed by you, of any of the following facilities, including, but not limited to, notes, photographs, documents collected, video recordings, audio recordings, emails, travel receipts, itineraries, visa requests, and the like
  - a. Xunqiao (FEI: 3003999190)
  - **b.** Chuannan (FEI: 3003885745)

# **EXHIBIT A-50**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: SDS Environmental Services, 115 Route 46, Building E-37, Mountain Lakes, NJ 07046

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

testing, or sampling of the material. See attached Se.	reduce 11
Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMAN	NDED to permit entry onto the designated premises,
1	you at the time, date and location set forth below, so
1 1 11	vey, photograph, test, or sample the property of any
designated object or operation on it.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
, I	
Place:	Date and Time:
	45 are attached - Rule 45(c), relating to the place of
	as a person subject to a subpoena; and Rule 45(e) and
(g), relating to you duty to respond to this subpoens	and the potential consequences of not doing so.
Date: <u>10/15/2020</u>	
CLERK OF COUL	RT
	OR
Signature of Clerk or	Deputy Clerk Attorney's signature
The name address a mail address and telephone no	umber of the atterney representing the Plaintiffs who

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

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### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

## **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-51

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY **LITIGATION** 

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: SGS US Testing Co. Inc., 201 Route 17, North Rutherford, NJ 07070.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020
	NDED to permit entry onto the designated premises you at the time, date and location set forth below, so
	rvey, photograph, test, or sample the property of any
designated object or operation on it.	
Place:	Date and Time:
(g), relating to you duty to respond to this subpoen Date: _10/15/2020	as a person subject to a subpoena; and Rule 45(e) and a and the potential consequences of not doing so.
CLERK OF COU	RT
	OR Marlene J.
Goldenberg	
Signature of Clerk o	r Deputy Clerk Attorney's signature
The name, address, e-mail address, and telephone r have issued the requests or subpoena are:	number of the attorney representing the Plaintiffs, who
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 80	0 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, f@goldenberglaw.com (legal assistant):

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# SCHEDULE A

Document 652-5

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### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

Document 652-5

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-52

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Shiva Pharmacem Pvt, Ltd. c/o Seth Goldberg, 30 South 17th Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Goldenberg Law, PLLC, 600 Lasane Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by ye	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
	5 are attached – Rule 45(c), relating to the place of s a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
CLERK OF COUR	T
	OR
	/s/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-53**

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# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Snehaa Solvents, 404/405 Rajshree plaza opp. Shreyas Cinema L.B.S., LBS Marg, Ghatkopar West, Mumbai, Maharashtra 400086, India

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

o permit entry onto the designated premises ne time, date and location set forth below, so
otograph, test, or sample the property of any
and Time:
etached – Rule 45(c), relating to the place of son subject to a subpoena; and Rule 45(e) and e potential consequences of not doing so.
OR
Clerk Attorney's signature
.1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
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- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
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- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
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- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

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- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

## **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-54

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

have issued the requests or subpoena are:

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Solvias, Inc. Registered Agent, 2125 Center Avenue, Suite 507, Fort Lee, NK 07024

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	IDED to permit entry onto the designated premises, you at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
CLERK OF COOP	OR
	_/s/ Marlene J. Goldenberg
Signature of Clerk or	
The name, address, e-mail address, and telephone nu	umber of the attorney representing the Plaintiffs, who

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
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# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

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## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
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- 2. All communications between you and any Defendant concerning any toxicology assessment.
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- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
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- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

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- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
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- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
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# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-55**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Southern Testing & Research Laboratories, 3809 Airport Drive, Wilson, NC 27896.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55	00 LaSalle Avenue, Suite			
2100, minicapono, mi	5401	November 15, 2020		
Inspection of Premises: land or other property pose that the requesting party m designated object or operate	ay inspect, measure, surv	ou at the time, date and	location set forth	below, so
Place:		Date and Time:		
compliance; Rule 45(d), relating to you duty to r Date: 10/15/2020	· .	s a person subject to a su and the potential conseq	ibpoena; and Rule	45(e) and
	3444	OR		
Goldenberg	Signature of Clerk or I		Marlene Attorney's signature	<u>J.</u>

## RELEVANT PORTIONS OF FED. R. CIV. P. 45

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

## **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

Document 652-5

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

## Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

## **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-56

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

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IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Spectral Data Services Inc., 818 Pioneer Street, Champaign, IL 61820.

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

DI .	D . 17"
Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMANIand or other property possessed or controlled by you that the requesting party may inspect, measure, survive designated object or operation on it.	
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection as (g), relating to you duty to respond to this subpoena Date: 10/15/2020 CLERK OF COUR'	and the potential consequences of not doing so.
GEDINI OI GOON	OR
	/s/ Marlene J.
Goldenberg Signature of Clerk or I	
The name, address, e-mail address, and telephone numbers issued the requests or subpoena are: Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800	LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,
mjgoldenberg@goldenberglaw.com; scheriff@	<u>agoldenberglaw.com</u> (legal assistant);

# **RELEVANT PORTIONS OF FED. R. CIV. P. 45**

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- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
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- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
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# DOCUMENT TO BE PRODUCED

### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

# **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-57

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Stericycle Expert Solutions Registered Agent, 6026 Lakeside Blvd, Indianapolis, IN 46278

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite	
2150, Minneapolis, MN 55401	November 15, 2020
Inspection of Premises: YOU ARE COMMAN land or other property possessed or controlled by you that the requesting party may inspect, measure, survidesignated object or operation on it.	
Place:	Date and Time:
The following provisions of Fed. R. Civ. 45 compliance; Rule 45(d), relating to your protection at (g), relating to you duty to respond to this subpoena Date: 10/15/2020 CLERK OF COUR	and the potential consequences of not doing so.
	OR
Signature of Clerk or I	/s/ Marlene J. Goldenberg Deputy Clerk  Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com assistant); (legal valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless

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# (2) Claiming Privilege or Protection.

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

order discovery from such sources if the requesting party shows good cause, considering the

limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# SCHEDULE A

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drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by Stericycle, Inc. related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

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# **EXHIBIT A-58**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Stericylce, Global Corporate Headquarters, 2355 Waukegan Road, Bannockburn, IL 60015

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

The state of the s	To the
Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue,	
Suite 2150, Minneapolis, MN 55401	November 15, 2020
1	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so
1 1 1 1	vey, photograph, test, or sample the property of any
designated object or operation on it.	vey, photograph, test, or sample the property or any
designated object of operation on it.	
Place:	Date and Time:
Titee.	Date and Time.
The following provisions of Fed R Civ 4	5 are attached – Rule 45(c), relating to the place of
O 1	is a person subject to a subpoena; and Rule 45(e) and
(g), relating to you duty to respond to this subpoena	
Date: 10/15/2020	and the potential consequences of not doing so.
CLERK OF COUR	·T
CLERK OF COOK	OR
C: , (C) 1	/s/ Marlene J. Goldenberg
Signature of Clerk or	Deputy Clerk Attorney's signature
The name, address, e-mail address, and telephone nu	imber of the attorney representing the Plaintiffs, who

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

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# **SCHEDULE A**

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by Stericycle, Inc. related to any and all Sartan products.

# Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-59

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Tiefenbacher API + Ingredients Registered Agent, c/o Seth Goldberg, 30 South 17<sup>th</sup> Street, Philadelphia, PA 19103-4196

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020
IDED to permit entry onto the designated premises, you at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Date and Time:
5 are attached – Rule 45(c), relating to the place of as a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
OR
Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

### SCHEDULE A

Document 652-5

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#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-60

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

## SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Sipra Labs Limited, 7-2-1813/5/A, Adj. to Post Office, Industrial Estate, Sanathnagar Hyderabad - 500018, India

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Suite 2150, Minneapolis, MN 55401	November 15, 2020	
land or other property possessed or con	COMMANDED to permit entry onto the designated premistrolled by you at the time, date and location set forth below, asure, survey, photograph, test, or sample the property of a	so
Place:	Date and Time:	
compliance; Rule 45(d), relating to your 1	R. Civ. 45 are attached – Rule 45(c), relating to the place otection as a person subject to a subpoena; and Rule 45(e) a subpoena and the potential consequences of not doing so.	
	OF COURT OR	
Signature	of Clerk or Deputy Clerk  Attorney's signature	
71 11 11 1.		1

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
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  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
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- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

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- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
- 3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.

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- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by Stericycle, Inc. related to any and all Sartan products.

#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-61

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue,

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

## SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** ToxRox Consulting, LLC, c/o David Jacobson-Kram, PhD DABT, 5910 Chesterbrook Road, McLean, VA 22101

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Suite 2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled l	ANDED to permit entry onto the designated premises by you at the time, date and location set forth below, so survey, photograph, test, or sample the property of an
Place:	Date and Time:
compliance; Rule 45(d), relating to your protection	v. 45 are attached – Rule 45(c), relating to the place of on as a person subject to a subpoena; and Rule 45(e) and sena and the potential consequences of not doing so.  OURT'  OR
Signature of Clerk	/s/ Marlene J. Goldenberg /k or Deputy Clerk  Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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#### A. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- Documents sufficient to show when You were first retained by any Defendant with which you
  had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA
  advocacy or communication, public relations relating to the ARB drug recalls, or recall
  management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

#### Quarantine and/or Destruction

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- 5. All destruction certifications created related to any ARB products or API.

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- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

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- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

- Document 652-5 PageID: 16670
- 1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-62

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16672

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY **LITIGATION** 

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

#### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Vega Lifesciences PVT. LTD., 390/A&B SRILAKSHMI SAI PREST ROAD. NO. 33, VIVEKANANDA NAGAR COLONY, KUKATPALLY, HYDERABAD, INDIA

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

GoldenbergLaw, PLLC, 800	Date and Tim	e:
Goldenberghaw, Thie, 000	LaSalle Avenue,	
Suite 2150, Minneapolis, MN	N 55401 November 15	, 2020
land or other property posses	YOU ARE COMMANDED to permit seed or controlled by you at the time, inspect, measure, survey, photograph on it.	date and location set forth below, so
Place:	Date and Tim	e:
compliance; Rule 45(d), relatin	ions of Fed. R. Civ. 45 are attached - ng to your protection as a person subjection pond to this subpoena and the potential	ect to a subpoena; and Rule 45(e) and
compliance; Rule 45(d), relating (g), relating to you duty to res	ng to your protection as a person subje	ect to a subpoena; and Rule 45(e) and al consequences of not doing so.
compliance; Rule 45(d), relating (g), relating to you duty to res	ng to your protection as a person subjection pond to this subpoena and the potention—  CLERK OF COURT	ect to a subpoena; and Rule 45(e) and al consequences of not doing so.

valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

PageID: 16673

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

Document 652-5

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#### Α. **Definitions**

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# **EXHIBIT A-63**

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

**To:** Vigilate Biopharma Pvt Ltd., Plot No 52, 57, 1st Floor, Opp: Prerana Hospital, Balaji Nagar, Kakatpally, Hyderabad 500072, India

*Production*: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

Signature of Clerk or	r Deputy Clerk Attorney's signature
	OR
CLERK OF COUR	RT
(g), relating to you duty to respond to this subpoena Date:	1 , 1
The following provisions of Fed. R. Civ. 4 compliance; Rule 45(d), relating to your protection a	45 are attached – Rule 45(c), relating to the place as a person subject to a subpoena; and Rule 45(e) a
Place:	Date and Time:
that the requesting party may inspect, measure, sur designated object or operation on it.	
Inspection of Premises: YOU ARE COMMAN land or other property possessed or controlled by y	NDED to permit entry onto the designated premis
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

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- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include

electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
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- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
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#### **DOCUMENT TO BE PRODUCED**

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

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# Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.
- 4. All return authorization documents and/or communications received by You related to any and all Sartan products.

## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

# **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-64

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16694

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Place:

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: VXL Life Sciences Registered Agent, c/o Seth Goldberg, 30 South 17th Street, Philadelphia, PA 19103-4196

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

2150, Minneapolis, MN 55401	November 15, 2020
land or other property possessed or controlled by y	DED to permit entry onto the designated premises, ou at the time, date and location set forth below, so vey, photograph, test, or sample the property of any
Place:	Date and Time:
	5 are attached – Rule 45(c), relating to the place of s a person subject to a subpoena; and Rule 45(e) and and the potential consequences of not doing so.
CLERK OF COUR	T ORS/ Marlene J. Goldenberg
Signature of Clerk or I	Deputy Clerk Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, migoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

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- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
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  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# **SCHEDULE A**

Document 652-5

PageID: 16698

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- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

# **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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## Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

# **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

# Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

Document 652-5

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

## **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-65

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16705

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY **LITIGATION** 

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

# SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: WRB Corp., 475 Steamboat Road, Greenwich, CT 06830.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:		Date and Time:			
GoldenbergLaw, PLLC, 800 I	aSalle Avenue, Suite				
2150, Minneapolis, MN 55403		November 15, 20	20		
Inspection of Premises: You land or other property possess that the requesting party may idesignated object or operation	ed or controlled by yourspect, measure, surv	ou at the time, date	and location	on set forth belo	ow, so
Place:	Date and Time:				
The following provision compliance; Rule 45(d), relating (g), relating to you duty to respondate: 10/15/2020	g to your protection as	s a person subject t	o a subpoe	na; and Rule 45(	e) and
	CLERK OF COUR'	Т			
		OR			
			<u>/s/</u>	Marlene	J.
<u>Goldenberg</u>					
	Signature of Clerk or Deputy		Attorney's signature		
The name, address, e-mail addr have issued the requests or sub Marlene J. Goldenberg, Golden	poena are:				

scheriff@goldenberglaw.com

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld*. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

## **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: In re: Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

# DOCUMENT TO BE PRODUCED

# **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-66

#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16716

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

have issued the requests or subpoena are:

migoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

#### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Zhejiang Menovo Pharmaceutical Co., Ltd., 8 Jingshisan Rd, Shangyu District, Shaoxing, Zhejiang, China.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

land or other property pos	s: YOU ARE COMMANDED to permit of sessed or controlled by you at the time, day inspect, measure, survey, photograph, tion on it.	ate and location set forth below, so
Place:	Date and Time:	
compliance; Rule 45(d), rel	visions of Fed. R. Civ. 45 are attached – ating to your protection as a person subject respond to this subpoena and the potential ————————————————————————————————————	et to a subpoena; and Rule 45(e) and
	Signature of Clerk or Deputy Clerk	Attorney's signature
The name, address, e-mail a	address, and telephone number of the attor	rney representing the Plaintiffs, who

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
    - (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
      - (i) is a party or a party's officer; or
      - (ii) is commanded to attend a trial and would not incur substantial expense.
    - (2) For Other Discovery. A subpoena may command:
    - (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
      - (B) inspection of premises at the premises to be inspected.
- (d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.
  - (1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.
    - (2) Command to Produce Materials or Permit Inspection.
    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
      - (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (i) fails to allow a reasonable time to comply;
  - (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
    - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
  - (i) disclosing a trade secret or other confidential research, development, or commercial information; or
  - (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
  - (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
    - (ii) ensures that the subpoenaed person will be reasonably compensated.
- (e) DUTIES IN RESPONDING TO A SUBPOENA.
  - (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
    - (A) *Documents*. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
    - (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
    - (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information*. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

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- (2) Claiming Privilege or Protection.
- (A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
  - (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) *Information Produced*. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

#### A. Definitions

- 1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).
- 2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.
- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

- 6. "FDA" means the United States Food & Drug Administration.
- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

- compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.
- 14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### DOCUMENT TO BE PRODUCED

#### **Corporate Organization**

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

#### **Contracts**

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

- drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

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3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

#### Communications with Relevant Parties

- 1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
- 2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
  - a. Date
  - b. Recipients and/or Senders of the Communication
  - c. General Subject Matter
  - d. Basis of Privilege

#### ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

#### **Nitrosamine Contamination**

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.

#### **Recall-Related Documents**

- 1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
- 2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
- 3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

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#### Quarantine and/or Destruction

- 1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
- 2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
- 3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
- 4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
- 5. All destruction certifications created related to any ARB products or API.

#### Communications with the FDA

- 1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
- 2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
- 3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
- 4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
- 6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

#### **Testing Data**

- 1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
- 2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
- 3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
- 4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

### Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

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- 2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
- 5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
- 6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

#### **Toxicology Assessments**

- 1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

# EXHIBIT A-67

#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Document 652-5

PageID: 16727

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION

Goldenberg Law, PLLC, 800 LaSalle Avenue, Suite

2150, Minneapolis, MN 55401

have issued the requests or subpoena are:

mjgoldenberg@goldenberglaw.com;

valsartan@csdisco.com (ESI Vendor).

No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

(legal

assistant);

#### SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Zi Qiang Gu, c/o Seth Goldberg, esq., Duane Morris 30 South 17th Street, Philadelphia, PA 19103-4196

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Date and Time:

November 15, 2020

Inspection of Premis	es: YOU ARE COMMAN	IDED to permit	entry onto the designated premises,
land or other property pe	ossessed or controlled by y	ou at the time, d	ate and location set forth below, so
that the requesting party	may inspect, measure, sur	vey, photograph,	test, or sample the property of any
designated object or oper	ration on it.	,,,,	
Place:		Date and Time	
Place:		Date and Time.	
		1	
0 1			Rule 45(c), relating to the place of ct to a subpoena; and Rule 45(e) and
± , , ,	~		l consequences of not doing so.
Date: 10/15/2020	P	F	I
	CLERK OF COUR	RT	
		OR	
			/s/ Marlene J. Goldenberg
	Signature of Clerk or	Deputy Clerk	Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402,

scheriff@goldenberglaw.com

#### RELEVANT PORTIONS OF FED. R. CIV. P. 45

- (c) PLACE OF COMPLIANCE.
  - (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
    - (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
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      - (i) is a party or a party's officer; or
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    - (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
    - (B) *Objections*. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
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- (g) CONTEMPT. The court for the district where compliance is required and also, after a motion is transferred, the issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

#### **SCHEDULE A**

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- 3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.
- 4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.
- 5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

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- 7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.
- 8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.
- 9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
- 10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.
- 11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.
- 12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).
- 13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

#### **DOCUMENT TO BE PRODUCED**

#### Agreements and CV

- 1. A copy of your most recent Curriculum Vitae.
- 2. Produce all formal and informal agreements, contracts, or licenses that You were/are a party to, with regard to (1) testing, (2) purity and contamination, (3) quality assurance, (4) risk assessment, (5) compliance with current Good Manufacturing Practices, (6) safety, (7) communications with regulatory agencies, (8) formulation, (9) production, (10) distribution, (11) packaging, (12) evaluation, (13) facility audits, with regard Defendant ZHP, orany Sartan and/or any Sartan ingredient.
- 3. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication.
- 4. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication.
- 5. Any contracts within your possession for services to be provided to Defendant ZHP by any other third parties (such as additional cGMP consultants (including, but not limited to Douglas Campbell), outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

6.

7.

#### **Communications with Other Third Parties**

- 1. All communications between you and Peter Saxon regarding ZHP or the nitrosamine contamination.
- 2. All documents and/or communications exchanged between You and Douglas Campbell, or any person or entity working for him, regarding ZHP or the Nitrosamine contamination.
- 3. All documents and/or communications exchanged between You and Frederick Ball, or any person or entity working for him, regarding ZHP or the Nitrosamine contamination.
- 4. All documents and/or communications exchanged between You and Charles Wang, or any person or entity working for him, regarding ZHP or the Nitrosamine contamination.
- 5. All documents and/or communications exchanged between You and Derek Zhang, or any person or entity working for him, regarding ZHP or the Nitrosamine contamination.
- 6. A All documents and/or communications exchanged between You and Dylan Yao, or any person or entity working for him, regarding ZHP or the Nitrosamine contamination.

#### Nitrosamine Contamination

- 1. All communications between you and any Defendant relating to nitrosamines.
- 2. All communications between you and any Defendant concerning any toxicology assessment.
- 3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
- 4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
- 5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
- 6. All draft reports edited by you for comment and provided to any Defendant.
- 7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
- 8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
- 9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
- 10. All documents or communications relating to nitrosamine testing of any drug.
- 11. All communications between you and ZHP regarding the FDA's investigation into the Nitrosamine Contamination.
- 12. All documents (either in final or draft form) in your possession regarding the FDA's investigation into the Nitrosamine contamination.
- 13. All notes taken during meetings and/or phone calls with the FDA regarding the nitrosamine contamination.
- 14. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination and/or ZHP's manufacture of any Sartan.
- 15. Copies of all testing provided to you by any Defendant (or third party retained by any Defendant) related to the testing of product for nitrosamine contamination.
- 16. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

- a. Date
- b. Recipients and/or Senders of the Communication
- c. General Subject Matter
- d. Basis of Privilege

#### Communications with the FDA

- 1. All documents related to any communications made between you, Defendant ZHP, and/or the FDA relating to any ANDA or DMF for any ARB held by Defendant ZHP, the facilities used to manufacture such products, and/or the nitrosamine contamination more generally, including emails, notes, memoranda and agendas since 2012.
- 2. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
- 1. by You, and Relevant Party, or any Third Party Laboratory retained by you.

#### **Inspection Documents**

- 1. All communications between You and ZHP regarding the FDA inspections of the following ZHP Facilities, including inspections conducted as part of the review and approval of ANDA Application Nos. 204821 (Valsartan) and 206083 (Valsartan HCTZ):
  - a. Xunqiao (FEI: 3003999190)
  - b. Chuannan (FEI: 3003885745)
- 2. All communications between You and employees at the FDA, including but not limited to, Milind Ganjawala, regarding inspections related to the following ZHP facilities:
  - a. Xunqiao (FEI: 3003999190)
  - b. Chuannan (FEI: 3003885745)
- 3. All documents related to any FDA inspection conducted by You, or witnessed by you, of any of the following facilities, including, but not limited to, notes, photographs, documents collected, video recordings, audio recordings, emails, travel receipts, itineraries, visa requests, and the like
  - a. Xunqiao (FEI: 3003999190)
  - b. Chuannan (FEI: 3003885745)
- 4. All documents (including all notes taken, memoranda, photographs) related to any audits or investigations conducted by you, or discussed with you, into manufacturing deviations at the following facilities:
  - a. Xunqiao (FEI: 3003999190) b. Chuannan (FEI: 3003885745)

- 1. All documents related to the January 29-31 inspection conducted by You of
- FEI:3003885745, including, but not limited to, notes, photographs, documents collected, video recordings, and audio recordings.All documents sufficient to show all persons You interacted with or spoke with during the

January 29-31, 2019 Audit of the ZHP facility Chuannan (FEI:3003885745).

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- 3. All documents in your possession collected during the January 29-31, 2019 Audit of the ZHP facility Chuannan (FEI: 3003885745) including, but not limited to all documents cited in Your April 29, 2019 Final Report at Section 4.2.
- 4. All Communications between You and Douglas Campbell regarding the January 29-31, 2019 Audit of the ZHP facility Chuanna (FEI: 3003885741).
- 5. All documents related to you travel to China for the January 29-31, 2019 Audit of the ZHP facility Chuannan (FEI:3003885745), including, but not limited to receipts, flight and travel itineraries, visa requests, and hotel invoices.

#### March 8-9 Audit of the ZHP facility Chuannan (FEI: 3003885745).

- 1. All documents related to the March 8-9, 2019 inspection conducted by You of the ZHP facility Chuannan (FEI:3003885745), including, but not limited to all notes, photographs, documents collected, video recordings and audio recordings.
- 2. All documents sufficient to show all persons You interacted with or spoke with during the Mach 8-9, 2019 Audit of the ZHP facility Chuannan (FEI:3003885745).
- 3. All documents in Your possession that were collected during the March 8-9, 2019 Audit of the ZHP facility Chuannan (FEI:3003885745) including, but not limited to all document cited in Your April 29, 2019 Final Report at Section 4.2.
- 4. All communications between you and Douglas Campbell regarding the March 8-9, 2019 Audit of the ZHP facility Chuannan (FEI:3003885745).
- 5. All documents related to you travel to China for the March 8-9, 2019 Audit of the ZHP facility Chuannan (FEI:3003885745), including, but not limited to receipts, flight and travel itineraries, visa requests, and hotel invoices.

#### **Evaluation of Quality Management System and CAPAs**

- 1. All communications between You, Douglas Campbell, employees at ZHP, and/or employees at Duane Morris regarding the April 29, 2019 Audit Report prepared by You and Douglass Campbell for ZHP.
- 2. All documents reviewed and/or collected by you in preparation for your creation of the April 29, 2019 Audit Report.
- 3. All draft versions of the April 29, 2091, Audit Report in Your possession.

### Your Evaluation of the Management System and Corrective and Preventative Actions

- 1. All documents between You and Douglas Campbell or any other employees of ZHP related to the April 29, 2019 Audit Report prepared by You and Douglas Campbell for ZHP.
- 2. All documents between You and Duane Morris or any other employees of ZHP related to the April 29, 2019 Audit Report prepared by You and Douglas Campbell for ZHP.
- 3. All document You review or collected in preparation of the April 29, 2019 Audit Report prepared for ZHP.
- 4. All drafts of the April 29, 2019 Audit Report.